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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,591	01/17/2006	Surachai Supattapone	DC0258US.NP	6069
26259	7590	12/29/2008		
LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			EXAMINER BABIC, CHRISTOPHER M	
			ART UNIT 1637	PAPER NUMBER
			NOTIFICATION DATE 12/29/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No. 10/553,591	Applicant(s) SUPATTAPONE ET AL.	
	Examiner CHRISTOPHER M. BABIC	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claim(s) 4 and 5 are pending. The following Office Action is in response to Applicant's communication dated September 15, 2008.

Claim Rejections - 35 USC § 101 - Withdrawn

Applicant has cancelled claim 1 rendering the previous rejection moot.

Claim Rejections - 35 USC § 102 - Withdrawn

Applicant has cancelled claim 1 rendering the previous rejection moot.

Claim Rejections - 35 USC § 112 - New Matter - Written Description - Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim(s) 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirements.

Initially, it is noted that when examining for compliance under the 35 USC 112, first paragraph requirements, the scope of the claimed invention must be considered. In the instant case, the claimed invention encompasses a composition consisting of

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ribonucleic acid molecules which enhance a specific prion transformation. Thus, the composition excludes any molecule, including those of RNA, that does not enhance the specific prion transformation (see MPEP 2111.03).

With regard to the written description requirement, the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the limitation reciting, "...consisting of ribonucleic acid molecules enhance...", added in Applicant's response dated September 15, 2008, was not contemplated in the disclosure at the time the application was filed, and thus, is new matter.

Applicant points to pg. 6-7 of the disclosure as providing support for this amendment; however, these portions are not considered to explicitly or inherently provide support for the above amendment because the cited experiments do not confirm that every molecule in the RNA compositions actually enhance the PrP^C to PrP^{Sc}. While the examiner agrees that Applicant has provided evidence of the general or relative requirements of the RNA molecules responsible for enhancing amplification of PrP^{Sc} (pg. 7, lines 15-25, "greater than 100,000 MW" and "may contain a poly(a) tail"; pg. 9-10, including ranges of polynucleotides lengths and natural sources), such evidence does not constitute even one absolute molecular structure of the claimed characteristic. Furthermore, the examiner can find no other evidence in the specification, including the SELEX-type binding (pg. 9) and size fractionation (pg. 20)

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experiments, that provide evidence of an absolute RNA structure. Such a structure would have been required at the time of invention to possess a composition consisting of only that RNA molecule which possesses the claimed characteristic.

With regard to the enablement requirement, the information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. In the instant case, since the specification does not provide evidence of even one absolute molecular structure of an RNA molecule responsible for enhancing amplification of PrP^{Sc}, Applicant's disclosure cannot possibly provide a meaningful method for making a composition consisting of only that RNA molecule which possesses the claimed characteristic.

While one could argue that a skilled artisan based on Applicant's disclosure could elucidate individual molecules of RNA that are responsible for enhancing amplification of PrP^{Sc}, the examiner is of the opinion that such experimentation is of an undue nature. Not only does the genus of RNA molecules that potentially enhance the amplification of PrP^{Sc} comprise millions upon millions of constituents, there is no evidence in the art or the specification of degree of predictability from one molecule to the next.

Prior Art Search

A search of the prior art found no reference teaching or suggesting a composition consisting of only an RNA molecule responsible for enhancing amplification of PrP^{Sc}.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

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